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Quality of Life and Physical Capacity of Older Ambulatory Adults with Rate-Controlled Atrial Fibrillation

A Thesis Submitted to the
Yale University School of Medicine
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ABSTRACT

Quality of Life and Physical Capacity of Older Ambulatory Adults with Rate-Controlled Atrial Fibrillation

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Although previous studies demonstrate that patients with atrial fibrillation (AF) refractory to rate-control are significantly impaired, quality of life (QOL) and physical capacity have yet to be adequately defined in rate-controlled AF patients.

Older ambulatory adults were recruited from the Veterans Administration Medical Center (VAMC) in West Haven, Connecticut. Forty-seven patients with AF were enrolled from the Coumadin clinic, and an equal number of age-matched veterans in normal sinus rhythm (NSR) were enrolled from the Primary Care Practice (PCP) clinic.

QOL was assessed by the widely-published Short Form Health Survey (SF-36) which has been validated in older adult and veteran populations. The SF-36 produces two summary scales, the Physical Component Summary (PCS) and the Mental Component Summary (MCS), which correlate positively with the level of physical and mental health QOL, respectively.

Physical capacity was assessed by the Yale Physical Activity Survey (YPAS), which has been validated in older adults. The YPAS produces a Summary Index, which correlates with physical capacity. The Summary Index takes frequency, duration, and intensity into consideration for several broad categories of physical activity specific for older adults. The total time spent on all physical activities over a one-week period is derived from the YPAS as well.

The results of the SF-36 gave PCS scores of 44.0 for the AF group and 44.7 for the NSR group. The MCS scores were 53.7 for the AF group and 54.8 for the NSR group.

As for the results of the YPAS, the Summary Index was 27.7 for the AF group and 27.5 for the NSR group. The Total Time for physical activities was 21.1 hours per week for the AF group and 21.8 hours per week for the NSR group. There were no statistically significant differences between the AF group and the NSR group in terms of the SF-36 scales and the YPAS indices.

Rate-controlled AF patients demonstrate QOL and physical capacity equal to comparable patients in NSR. The data suggest that maintenance of NSR improves neither QOL nor physical capacity in rate-controlled AF patients. Rhythm control may not be necessary in patients who can be managed with anticoagulation and rate-control. Ongoing randomized trials, including the Atrial Fibrillation Follow-up Investigation of Rhythm Management (AFFIRM) study, will further address appropriate management of atrial fibrillation.

ACKNOWLEDGEMENTS

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INTRODUCTION

AF is the most common cardiac arrhythmia, and is of particular importance in older adults of Western societies. Over the age of 60, AF has a prevalence of 2-4%.[1] AF may affect as many as 16% of men and 12.2% of women over the age of 75.[2,3]

AF is associated with substantial morbidity and mortality. The relative risk of stroke in nonvalvular AF is 5.6 times increased over patients in NSR. Coexistent rheumatic valvular disease such as mitral stenosis, increases the relative risk of stroke to 17-fold.[4] The one-year recurrence risk of stroke for AF patients is on the order of 15% or more.[5,6,7,8,9] The all-cause mortality of patients in AF is increased more than two-fold.[10,11]

QOL in AF is less well defined because only a limited number of studies have been published. The studies to date have primarily focused upon inadequately rate-controlled AF patients in whom atrioventricular-node (AV) ablation was planned. Fitzpatrick et al[12] retrospectively studied QOL in 107 patients who had undergone AV-nodal ablation with pacemaker placement. The patients were in either chronic AF or paroxysmal atrial fibrillation (PAF). QOL was assessed both before and following treatment by a customized survey, activities of daily living (ADL's), symptoms, health care consumption, and significant health events. The customized QOL survey asked patients to rate general QOL on a scale from very poor to excellent, and to rate any change in QOL on a scale from much worse to much better. ADL's were assessed by asking patients to rate the degree of physical limitation with vigorous exercise, moderate exercise, carrying groceries, climbing stairs, walking, and bathing/dressing. Possible answer choices included not limited at all, limited a little, or very limited. For health care consumption, patients reported the number of emergency room visits, hospital

admissions, and doctor visits. In terms of significant health events, patients reported episodes of heart failure, stroke, and the need for anticoagulation. Significant health events were confirmed either by chart review or by the primary medical doctor. Patients reported an increase in QOL from poor prior to AV-nodal ablation and cardiac pacing, to good/very good afterwards. The change in QOL was reported as only slightly improved. The reported frequency of significant symptoms decreased from very frequent/sometimes before, to infrequent after the procedure. The reported effect of symptoms on QOL decreased from severe to little effect afterwards. The ADL's were reported as limited a little at baseline, and improved to not limited/limited a little with treatment. As for health care consumption, hospital admissions decreased from 2.8 to 0.2 annually. Emergency room visits declined from 3.1 to 0.2 annually. There were 19 confirmed cases of congestive heart failure before treatment, and 8 cases afterwards. 12 strokes were reported pre-treatment, and 3 strokes following treatment.

Natale *et al*[13] prospectively studied QOL in AF patients undergoing AV-nodal ablation with pacemaker implantation. QOL was determined pre-procedure and at 12-months follow-up. Patients were asked to rate the severity of palpitations, rest dyspnea, effort dyspnea, exercise limitation, and weakness. Symptoms were rated on a scale from 0 (absent) to 5 (extremely severe). Patients also rated well-being on a scale from 1 (poor) to 5 (excellent). The New York Heart Association (NYHA) Functional classification was assessed as well. With treatment, symptom severity decreased significantly. For example, the self-reported severity of effort dyspnea decreased from a score of 3.4 to1.8, and exercise limitation from a score of 3.5 to 1.7, at 12-months follow-up. The NYHA functional classification decreased from a mean of 2.6 to 1.7 afterwards.

The self-reported general well-being score improved from 1.8 to 3.4 at 12 months post-procedure.

Bubien *et al*[14] prospectively studied QOL of patients with recurrent symptomatic arrhythmias—both supraventricular and ventricular—before and after AV-nodal ablation. QOL was assessed by the Short Form Health Survey (SF-36), symptoms, and ADL's.

The SF-36 consists of a series of 36 multiple-choice questions. The answer choices are scored by an algorithm that generates the following 8 primary scales on distinct aspects of QOL: Physical Functioning, Role-Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role-Emotional, and Mental Health. The scores for each scale range from 0 (the lowest QOL) to 100 (the highest QOL).

The Physical Functioning (PF) scale reflects the patient's ability to perform all types of physical activities including vigorous activities without any limitation due to health. The Role-Physical (RP) scale indicates the degree of impairment in performing work or other daily activities due to physical health. The Bodily Pain (BP) scale ascertains severity of limitation due to bodily pain. The General Health (GH) scale is derived from a self-reported evaluation of personal health. The Vitality (VT) scale reflects the degree of pep and energy. The Social Functioning (SF) scale suggests the ability to do normal social activities without interference from physical or emotional problems. The Role-Emotional (RE) scale gauges limitation in work or daily activities due to emotional problems. Finally, the Mental Health (MH) scale indicates the degree to which the patient feels peaceful, happy and calm.

The following two summary scales are generated by a secondary algorithm: the Physical Component Summary (PCS) and the Mental Component Summary (MCS). The

component summary scales are distinct from the 8 primary scales because the PCS and MCS have been normalized to a mean score of 50 and a standard deviation (SD) of 10 in the general population. Again, higher scores indicate better QOL. The PCS reflects physical limitation, disability, well-being, and energy level. The MCS reflects psychological distress, affect, and limitation in social activities due to emotional problems

As for symptoms, patients rated frequency on a scale from 0 to 64, and severity on a scale from 0 to 48. Higher symptom scores indicate greater impairment. As for ADL's, patients rated the impact of arrhythmia, from 0 (severe impairment) to 100 (no impairment), on daily activities. The performance of ADL's was also determined by a series of 9 questions concerning the ability to do routine physical, social, and family activities.

Following AV-nodal ablation, the QOL in AF patients improved significantly. On the SF-36, for example, Physical Functioning increased from a score of 34 to 52, and Role-Physical increased from a score of 7 to 36. The perceived impact on ADL's improved from a score of 8 to 44. As for symptoms, the frequency score decreased from 34 to 19, and the severity score decreased from 26 to 14.

Finally, Rosenquist et al[15] prospectively studied QOL in 47 patients with intractable disabling supraventricular arrhythmias before and after AV-nodal ablation. Patients were followed for a mean period of 41 months. Of the study population, 59% had either atrial fibrillation or atrial flutter. QOL was assessed by symptoms, health care utilization, activity level, and NYHA classification. Both the presence of symptoms and the frequency of symptoms were assessed. Health care utilization was gauged by the

annual number of hospital admissions. As for activity level, patients were asked whether the level of activity had improved following AV-nodal ablation. Palpitations were reported in 100% of the seven patients in whom AV-nodal ablation was not complete compared to 26% of the patients in whom AV-nodal ablation was complete. The number of hospital admissions decreased from 2.4 to 0.3 annually. 83% of the patients with successful AV-nodal ablations reported an improved activity level. AF refractory to anticoagulation and rate-control appears to significantly impair QOL. However, the effect of rate-controlled AF on QOL is not yet known.

STATEMENT OF PURPOSE

This study will test the hypothesis that rate-controlled AF impairs QOL and physical capacity in older ambulatory adults.

Assuming AF impairs QOL, cardioversion to NSR should lead to improved QOL. In AF, direct current (DC) cardioversion restores NSR in 67 to 90% of patients.[16,17,18,19] However, only about 37% of successful cardioversions will remain in NSR at one-year follow-up. The success of DC cardioversion is decreased with the duration of AF (on the order of years) and the left atrial dimension (greater than 6 centimeters).

Pharmacologic agents which maintain NSR include Class I and Class III antiarrhythmics. With either quinidine or sotolol, 48-52% of AF patients will remain in NSR after DC cardioversion and antiarrhythmic therapy at six months follow-up.[20] However, 55% of successfully cardioverted patients on quinidine will have reverted back to AF at 15 months follow-up.[21] Low-dose amiodarone with DC cardioversion restores NSR in 59 to 90% of AF patients.[22,23,24] With amiodarone, about 53% of successfully cardioverted AF patients will have maintained NSR at 3 years follow-up.[25]

However, the adverse effects of antiarrhythmic therapy are significant. There is a three-fold increase in mortality with quinidine, especially in hypokalemic patients who are at risk for ventricular fibrillation.[26,27] Both Class I and Class III antiarrhythmics may induce the polymorphic ventricular tachycardia "torsades de pointes" which terminates fatally in half the cases.[28,29] Amiodarone has been reported to cause pulmonary fibrosis in 5 to 15% of patients.[30] Although DC cardioversion plus antiarrhythmic therapy may successfully maintain NSR, many patients revert to AF and the adverse effects of antiarrhythmic therapy can be life threatening.

The benefits of converting an AF patient to NSR, such as potentially improved QOL and physical capacity, must be weighed against the significant adverse effects of antiarrhythmic therapy.

METHODS

Recruitment

Non-institutionalized older ambulatory adults were recruited from the Veterans Affairs Medical Center (VAMC) in West Haven, Connecticut. AF patients were recruited from a list of 291 patients who have been chronically anticoagulated within the previous twelve months. Study investigators recruited AF patients who were over the age of 60 from Coumadin Clinic.

NSR patients were all recruited from the Primary Care Practice (PCP) clinic. NSR patients who age-matched currently enrolled unmatched AF patients were selectively recruited. Patients were considered age-matched if the years of birth were within one year.

Eligible patients who were willing to participate in the study signed an informed consent form approved by the Internal Review Board at the VAMC. Patient charts were then reviewed in order to confirm enrollment eligibility.

Rhythm Definitions

AF was defined as persistent AF without any evidence of NSR over the previous six-month period. Conversely, NSR was defined as persistent NSR over the same period without any evidence of AF or symptomatic ventricular arrhythmias. Cardiac rhythms were documented by chart review as well as electrocardiogram and 24-hour holter monitoring.

Study Criteria

All non-institutionalized ambulatory patients over the age of 60 who were stable (refer to Table 1) were eligible to participate. Patients were excluded if there were any

non-elective hospitalizations or any coronary revascularization procedure within the

previous six months. Patients were excluded for debilitating disease such as severe CHF

(NYHA class III or IV), oxygen-dependent chronic obstructive pulmonary disease

(COPD), or any terminal illness with a life-expectancy of less than six months.

TABLE 1   ENROLLMENT CRITERIA

INCLUSION

1. Is the patient 60 years old or older?
2. Is the patient ambulatory?

EXCLUSION

1. Has the patient been hospitalized within the past six months for a non-elective admission?
2. Has the patient undergone percutaneous transluminal coronary angioplasty (PTCA) within the previous six months?
3. Has the patient had Coronary Artery Bypass Grafting (CABG) in the previous six months?
4. If the patient is in AF, is there any evidence of sinus rhythm within the previous six months?
5. Does the patient have NYHA Class III or Class IV congestive heart failure (CHF)?
6. Does the patient have symptomatic ventricular arrhythmias?
7. Does the patient have debilitating liver disease?
8. Does the patient have debilitating pulmonary disease (steroid-dependent within the previous 6 months, or an FEV1 of less than 1 liter)
9. Is the patient dependent on supplemental oxygen?
10. If the patient is in AF, is cardioversion planned in the near future?
11. Does the patient have a creatinine greater than 3.0?
12. Does the patient have a hematocrit of less than 28?
13. Is the patient a nursing home resident?
14. Does the patient have a terminal disease with a life expectancy of less than six months?
15. Is the patient currently taking any Class I or Class III antiarrhythmics?
16. Is the patient blind?

Comorbid Conditions

Coexisting medical conditions were assessed by the widely used Charlson

Comorbidity Index[31] (refer to Appendix A). Charlson *et al* studied the effects of

comorbid conditions on mortality. Comorbidities were assigned weights according to

impact on the mortality rate (refer to Table 2). The Charlson Comorbidity Index is the

aggregate sum of the assigned weights for all medical conditions present, and correlates

with the degree of comorbidity.

TABLE 2   CHARLSON COMORBIDITY WEIGHTS

Medical history	Assigned weight
Myocardial infarction Congestive heart failure Peripheral vascular disease Cerebrovascular disease Dementia Chronic pulmonary disease Connective tissue disease Ulcer disease Mild liver disease Diabetes	1
Hemiplegia Moderate or severe renal disease Diabetes with end-organ damage Any tumor Leukemia Lymphoma	2
Moderate or severe liver disease	3
Metastatic solid tumor Acquired immune deficiency	6

Medications

As a proxy for comorbidity, the number and type of prescribed medications were

recorded (refer to Appendix B). Active prescriptions were determined from the

decentralized hospital computer program (DHCP) at the VAMC.

Demographics

Demographic data and social history were recorded onto a customized survey

form (refer to Appendix D).

Quality of Life

Study investigators conducted the Short Form Health Survey (SF-36, refer to

Appendix E)[32] by in-person interview in order to assess QOL. The SF-36 has been

validated as a tool for measuring QOL in older adults.[33,34,35] Older adults may, however,

require greater assistance in completing the SF-36[36,37] as provided by in-person interview.

Kazis *et al*[38] validated the SF-36 among veteran populations as part of the Veterans

Health Study. Subsequently, the Department of Veterans Affairs has adopted the SF-36

as a standard instrument for measuring QOL.[39]

The SF-36 measures QOL by the following 8 primary scales: Physical

Functioning (PF), Role-Physical (RP), Bodily Pain (BP), General Health (GH), Vitality

(VT), Social Functioning (SF), Role-Emotional (RE), and Mental Health (MH). Scores

for each scale range from 0 to 100, with a score of zero indicating poor QOL and a score

of 100 indicating high QOL. Table 3 further depicts specific health states that would

receive low and high scores on each of the SF-36 scales. The Physical Component

Summary (PCS) and a Mental Component Summary (MCS) are derived from the 8

primary scales. The PCS and MCS scores have been normalized to a mean of 50, and a

SD of 10 in the general population. Again, higher scores indicate increased QOL.

Physical Capacity

Physical capacity was assessed by the Yale Physical Activity Survey (YPAS).[40]

Previous physical activity surveys had been developed for young patients, however the

YPAS was specifically designed to assess the physical activity level in older patients

(refer to Appendix F). Since the YPAS includes low intensity activities specific for older

adults, the YPAS has the sensitivity to assess the full range of physical activity in older adult populations.

TABLE 3   SHORT FORM HEALTH SURVEY (SF-36) INTERPRETATION[41]

			Low score	High score
Summary scales	General population mean score=50 SD=10	Physical Component Summary (PCS)	Substantial limitations in self-care, physical, social, and role activities; severe body pain; frequent tiredness; rated health as "poor"	No physical limitations, disabilities, or decrements in well-being; high energy level; health rated as "excellent"
		Mental Component Summary (MCS)	Frequent psychosocial distress, substantial social and role disability due to emotional problems; health in general rated as "poor"	Frequent positive affect; absence of psychological distress and limitations in usual social or role activities due to emotional problems; health rated "excellent"
Primary scales	Maximum score=100 (high QOL) Minimum score=0 (poor QOL)	Physical Functioning (PF)	Limited a lot in performing all physical activities due to health	Performs all types of physical activities including the most vigorous without limitations due to health
		Role-Physical (RP)	Problems with work or other daily activities as a result of physical health	No problems with work or other daily activities as a result of physical health
		Bodily Pain (BP)	Very severe and extremely limiting pain	No pain, or no limitation due to pain
		General Health (GH)	Evaluates personal health as poor and believes it is likely to get worse	Evaluates personal health as excellent
		Vitality (VT)	Feels tired and worn out all of the time	Feels full of pep and energy all the time
		Social Functioning (SF)	Extreme and frequent interference with normal social activities due to physical or emotional problems	Performs normal social activities without interference due to physical or emotional problems
		Role-Emotional (RE)	Problems with work or other daily activities as a result of emotional problems	No problems with work or other daily activities as a result of emotional problems
		Mental Health (MH)	Feelings of nervousness and depression all the time	Feels peaceful, happy, and calm all of the time

The YPAS is a valid and reproducible instrument for measuring physical activity.[42] For example, the Summary Index has been shown to correlate with the estimated maximum oxygen consumption ($r=0.58$, $p=0.004$), and with percent body fat ($r=-0.43$, $p=0.003$).

The YPAS consists of two parts: the Activities Checklist and the Activities Dimensions. On the Activities Checklist, patients estimate the typical amount of time spent over a one-week period on specific physical activities. In order to standardize responses, patients were asked to consider only the previous 4 weeks. The patient may also list specific physical activities not already included on the Activities Checklist. The Activities Checklist estimates the total time and kilocalories[43,44] spent on physical activities over a one-week period.

The Activities Dimensions consist of a short series of multiple-choice questions. The Activities Dimensions were designed to quickly assess the spectrum of physical activity in older patients. An algorithm is applied to the answers for the multiple-choice questions to derive the following five indices: Vigorous Activity, Leisure Walking, Moving, Standing, and Sitting. These indices are unitless, and are weighted according to the intensity of physical activity. Higher scores reflect increased frequency, duration and intensity of physical activity. A Summary Index is derived by summing together scores for all five of the primary indices.

Sample Size

The necessary sample size for measuring specific differences on each of the SF-36 scales is depicted in Table 4. Because PCS and MCS scores are derived from the 8 primary SF-36 scales, the PCS and MCS scales have the greatest power in detecting

slight differences in QOL. With a sample size of 100, the study would have the power to distinguish a 3-point difference on the PCS and MCS scales. As for clinical significance, studies in the general population have demonstrated that diabetes depresses PCS by 3.44 points whereas allergy depresses PCS by 0.82 points[45] (refer to Table 15). Because a 3-point difference was considered clinically significant, a sample size of 100 was selected.

TABLE 4   SF-36 SAMPLE SIZE REQUIRED FOR CROSS-SECTIONAL STUDY[46,47]

	2-point difference	5-point difference	10-point difference	20-point difference
	Sample size (n)	Sample size (n)	Sample size (n)	Sample size (n)
Physical Component Summary (PCS)	394	64	18	6
Mental Component Summary (MCS)	394	64	18	6
Physical Functioning (PF)	2134	342	88	24
Role-Physical (RP)	4564	732	184	48
Bodily Pain (BP)	2206	354	90	24
General Health (GH)	1636	264	68	18
Vitality (VT)	1732	278	72	20
Social Functioning (SF)	2024	326	82	22
Role-Emotional (RE)	4304	690	174	44
Mental Health (MH)	1288	208	54	16

* Estimated sample sizes assume α=0.05, two-tailed t-test, and a power of 80%

Data Collection and Management

Data was recorded onto survey forms (refer to Appendices A to F), and then keypunched into an Oracle database. All of the computer data was manually checked against the survey forms, and any errors were corrected at that point.

The raw data was imported into Statistical Package Software Solutions (SPSS) on which the Charlson Comorbidity Index, the SF-36 scales, and the YPAS indices were calculated. The computer-generated scores were manually validated against a random sample of 5% of the patients.

Statistical Analysis

All of the statistical analyses were done on SPSS. Quantitative data was compared by two-tailed Student's t-test whereas qualitative data was compared by χ^2-test with Yates correction. The study data was compared to normative data for statistical significance by the Student's t-test using the pooled standard error. On the SF-36, the study SD was used to calculate statistical significance when comparing the study data to published data for which the SD was not known. For any specific scale of the SF-36, the SD tends to change minimally from group to group.[48] In order to discern the influence of comorbidity on the SF-36 and YPAS scores, Pearson correlation coefficients were calculated by the least-squares method. SF-36 scores were corrected for the effect of comorbidity by the least means squared method of linear regression.

Atrial Fibrillation Study

The QOL and Physical Capacity study is part of a larger project. A second medical student is studying the effects of AF on various physiologic parameters which includes 24-hour holter monitoring, exercise treadmill tests, pulmonary function tests and echocardiograms. As both studies examined the same set of patients, patients were recruited and charts were reviewed jointly. I had the primary responsibility for conducting patient interviews whereas the second medical student had the primary responsibility for coordinating the tests.

RESULTS

Exclusions

From 291 Coumadin Clinic patients, 30 patients refused and 129 were excluded (refer to Table 5). Major exclusions included recent non-elective hospitalization (25.2%), age less than 60 (13.2%), non-AF cardiac rhythm (10.7%), and pacemaker (14.5%).

From 430 PCP clinic patients, 40 patients refused and 343 were excluded. Major exclusions included age less than 60 (36.0%) and no enrolled AF age-match available (46.5%).

40 AF patients compared to 8 NSR patients were excluded for recent non-elective hospitalization. Inadequately rate-controlled AF patients may have been selectively excluded from the study due to sequelae such as CHF exacerbation and myocardial ischemia requiring hospitalization.

Demographics

94 patients were enrolled in the study. Study participants had a mean age of 75 years and an age range from 64 to 88 years old (refer to Table 6). 93 patients were male, 85 were Caucasian, and 9 were African-American. 87 lived independently either in a house or apartment whereas the other 7 lived with relatives. Only 15 of the patients were currently employed.

The only statistically significant difference of interest was the prevalence of alcohol use. 38.3% of the AF patients admitted to recent alcohol consumption in the previous six months compared to 68.1% of the NSR patients ($p < 0.01$).

TABLE 5   STUDY EXCLUSIONS

		Atrial Fibrillation number (%)	Normal Sinus Rhythm number (%)
Screening	Age (less than 60 years old)	21 (13.2)	138 (36.0)
	Over 60 years old, but no age-match	NA	178 (46.5)
	Recent Hospitalization	40 (25.2)	8 (2.1)
	Died prior to study	4 (2.5)	NA
Recruiting	Patient refused	30 (18.9)	40 (10.4)
	Non-ambulatory	11 (6.9)	3 (0.8)
	Paroxysmal Atrial Fibrillation	10 (6.3)	3 (0.8)
	Atrial Flutter	1 (0.6)	0 (0.0)
	Normal Sinus Rhythm	6 (3.8)	NA
	Pacemaker	23 (14.5)	1 (0.3)
	Recent Cardioversion	1 (0.6)	0 (0.0)
	Antiarrhythmic	1 (0.6)	2 (0.5)
	Left Bundle Branch Block	2 (1.3)	1 (0.3)
	Acute Myocardial Infarction	0 (0.0)	1 (0.3)
	Terminal Illness	4 (2.5)	0 (0.0)
	Severe COPD	1 (0.6)	4 (1.0)
	Chronic Renal Insufficiency (Cr>3.0)	1 (0.6)	2 (0.5)
	Blind	2 (1.3)	1 (0.3)
	Non-English Speaking	1 (0.6)	0 (0.0)
	Nursing Home Resident	0 (0.0)	1 (0.3)
	Total exclusions	159	383

Medical Conditions

The AF group had a mean of 4.4 ±2.1 medical conditions and the NSR group had a mean of 3.0 ±1.8 medical conditions (refer to Table 7). The AF and NSR patients enrolled in the study both demonstrated a significant level of comorbidity.

The Charlson Comorbidity Index was 2.6 in the AF group compared to 1.7 in the NSR group (p=0.05). The only medical conditions that had a higher prevalence in the AF group of statistical significance were solid tumor without metastases, CHF and arrhythmia. Arrhythmia does not to contribute to the Charlson Comorbidity Index. The

increased comorbidity in the AF group, in particular the increased solid tumor history,

may negatively impact the results of the SF-36 and the YPAS.

TABLE 6   STUDY DEMOGRAPHICS

	Atrial Fibrillation number (%)	Normal Sinus Rhythm number (%)
Study group size (n)	47	47
Age (years ±1.0 SD)	75.6 ±5.6	75.2 ±5.7
Male	46 (97.9)	47(100.0)
Female	1 (2.1)	0 (0.0)
Caucasian	44 (93.6)	41 (87.2)
African-American	3 (6.4)	6 (12.8)
Married	35 (74.5)	36 (76.6)
Lives alone	11 (23.4)	7 (14.9)
Lives in a house or apartment	44 (93.6)	43 (91.5)
Currently working	7 (14.9)	8 (17.0)
High school graduate	38 (80.9)	39 (83.0)
College graduate	6 (12.8)	6 (12.8)
Current alcohol use	18 (38.3)	32 (68.1) †
Current cigarette use	4 (8.5)	4 (8.5)
Previous cigarette use	23 (48.9)	32 (68.1)
Pack-years (years ±1.0 SD)	49.9 ±35.0	49.8 ±39.7

† p<0.01

Cardiac History

The AF group demonstrated reasonable rate-control with a mean heart rate of

73 ±11, and a maximal heart rate of 130 ±25 by 24-hour holter monitoring (refer to

Table 8). 25.5% of the AF patients and 29.8% of the NSR patients have a history of

angina pectoris. Only 29.8% of the AF patients have a history of either electrical or

chemical cardioversion. 14.9% of the AF patients and 17.1% of the NSR patients have

undergone coronary revascularization. 8.5% of AF patients versus 2.1% of NSR patients

(p>0.05) have a history of valvular heart disease. 8.5% of AF patients have a history of

thyroid disease (mostly hypothyroidism) compared to none of the NSR patients (p>0.05).

Whether the hypothyroidism in the AF group was a primary or secondary condition was not determined in the study.

TABLE 7   CHARLSON COMORBIDTY INDEX AND PAST MEDICAL HISTORY*

	Atrial Fibrillation n=47	Normal Sinus Rhythm n=47	
	number (%)	number (%)	
CHARLSON COMORBIDITY INDEX (mean ±1.0 SD)	2.6 ±2.0	1.7 ±1.9	†
MEDICAL CONDITIONS (mean number ±1.0 SD)	4.4 ±2.1	3.0 ±1.8	†††
Acquired immune deficiency	0 (0.0)	0 (0.0)	
Cerebrovascular disease	9 (19.1)	5 (10.6)	
Chronic pulmonary disease	11 (23.4)	10 (21.3)	
Congestive heart failure	14 (29.8)	4 (8.5)	††
Connective tissue disease	0 (0.0)	0 (0.0)	
Dementia	1 (2.1)	1 (2.1)	
Diabetes	15 (31.9)	14 (29.8)	
Diabetes with end-organ damage	2 (4.3)	2 (4.3)	
Hemiplegia	0 (0.0)	0 (0.0)	
Leukemia	0 (0.0)	0 (0.0)	
Liver disease (mild)	2 (4.3)	1 (2.1)	
Liver disease (moderate to severe)	0 (0.0)	0 (0.0)	
Lymphoma	1 (2.1)	0 (0.0)	
Metastatic solid tumor	1 (2.1)	1 (2.1)	
Myocardial infarction	13 (27.7)	11 (23.4)	
Peptic ulcer disease	6 (12.8)	8 (17.0)	
Peripheral vascular disease	11 (23.4)	7 (14.9)	
Renal disease (moderate to severe)	0 (0.0)	0 (0.0)	
Solid tumor without metastases	14 (29.8)	5 (10.6)	††

 * Refer to Appendix C for definitions of medical conditions
 † p=0.05
 †† p<0.05
 ††† p<0.001

Medications

For the AF patients, 95.7% were anticoagulated on warfarin and 93.6% were on a rate-controlling agent (refer to Table 9). 57.4% of AF patients were taking diuretics compared to 25.5% of the NSR patients.

SF-36

The SF-36 QOL scores for the AF group were compared to the NSR group as well as to sex and age-specific normative data[49] from the general population (refer to

TABLE 8   CARDIAC HISTORY

	Atrial Fibrillation n=47		Normal Sinus Rhythm n=47		
	number (%)		number (%)		
Mean heart rate (rate ±1.0 SD)	73 ±11		72 ±11		
Maximum heart rate (rate ±1.0 SD)	130 ±25		112 ±16		††
Angina	12	(25.5)	14	(29.8)	
Arrhythmia	47	(100.0)	2	(4.3)	††
Cardioversion attempted (electrical or chemical)	14	(29.8)	0	(0.0)	†
Coronary artery bypass grafting	5	(10.6)	6	(12.8)	
Hypercholesterolemia	18	(38.3)	24	(51.1)	
Hypertension	34	(72.3)	36	(76.6)	
Myocardial infarction	13	(27.7)	11	(23.4)	
Percutaneous transluminal coronary angioplasty	2	(4.3)	2	(4.3)	
Syncope	2	(4.3)	4	(8.5)	
Thyroid disorder	4	(8.5)	0	(0.0)	
Valvular heart disease	4	(8.5)	1	(2.1)	

† p<0.001
†† p<0.0001

TABLE 9   PATIENT MEDICATIONS

	Atrial Fibrillation		Normal Sinus Rhythm		
	number (%)		number (%)		
Medications taken (mean ±1.0 SD)	5.8 ±2.7		3.9 ±2.1	†	
Ace inhibitors	18	(38.3)	13	(27.7)	
Aspirin	0	(0.0)	14	(29.8) ††
AV-nodal rate-controlling agent	44	(93.6)	24	(51.0) ††
Bronchodilators	11	(23.4)	6	(12.8)
Diabetic medications	12	(25.5)	14	(29.8)
Diuretics	27	(57.4)	12	(25.5) †
Warfarin	45	(95.7)	1	(2.1) †††

† p<0.01
†† p<0.001
††† p<0.0001

Table 10). Although the SF-36 scores for the AF group were lower than the NSR group

by 0.02 to 0.40 SD, all of the differences were of no statistical significance (NS). In

comparison to age and sex-specific normative data, the NSR group's PCS and MCS

scores were 0.35 and 0.31 SD higher, respectively (p<0.05). The slightly increased QOL

in the NSR group is most likely because the general population normative data includes

patients with all cardiac rhythms as well as patients with debilitating disease. The AF

patients demonstrated QOL equal to the NSR patients in spite of the NSR patients having

a slightly higher than expected QOL.

TABLE 10   SHORT FORM HEALTH SURVEY (SF-36)

		Normative Data[*,50,51] n=293 (mean ±1.0 SD)	Atrial Fibrillation[&] n=47 (mean ±1.0 SD)	Normal Sinus Rhythm n=47 (mean ±1.0 SD)	
Summary scales	Physical Component Summary (PCS)	42.0 ±11.4	42.9 ±11.3	45.8 ±10.5	#
	Mental Component Summary (MCS)	52.5 ±9.8	53.2 ±8.8	55.3 ±8.5	#
Primary scales	Physical Functioning (PF)	65.8 ±28.3	67.7 ±28.6	75.9 ±26.8	#
	Role-Physical (RP)	59.7 ±42.5	59.6 ±39.5	71.8 ±37.8	#
	Bodily Pain (BP)	68.8 ±25.4	75.1 ±27.0	77.8 ±24.2	#
	General Health (GH)	58.6 ±22.1	64.9 ±20.6	67.6 ±20.3	##
	Vitality (VT)	57.8 ±22.6	56.6 ±28.5	63.9 ±21.9	
	Social Functioning (SF)	79.7 ±26.0	79.5 ±27.3	89.1 ±21.3	#
	Role-Emotional (RE)	76.9 ±37.5	83.7 ±31.8	94.3 ±20.0	###
	Mental Health (MH)	77.4 ±17.4	79.7 ±16.1	80.1 ±19.0	

  * Data for men over the age of 65 in the general population
  & p>0.05 when comparing the AF group with the NSR group and with the general population normative data on all SF-36 scales
  # p<0.05 for the NSR group compared with the general population normative data
  ## p<0.01 for the NSR group compared with the general population normative data
  ### p<0.0001 for the NSR group compared with the general population normative data

SF-36 Results for Inadequately Rate-Controlled Atrial Fibrillation

Previous studies demonstrated impaired QOL in poorly rate-controlled AF

patients prior to AV-nodal ablation.[52,53,54,55] The PCS and MCS scores for the poorly

rate-controlled AF patients from the Bubien et al study (n=22) were 1.1 SD and 1.7 SD,

respectively, below the rate-controlled AF patients in this study (refer to Table 11). The

AF patients examined in previous studies had such inadequate rate-control that

electrophysiologic procedures were planned. In contrast, the AF patients in this study

were medically managed on anticoagulation and rate-control.

TABLE 11 SF-36 COMPARISON OF INADEQUATELY RATE-CONTROLLED ATRIAL
FIBRILLATION VERSUS RATE-CONTROLLED ATRIAL FIBRILLATION

		Inadequately Rate-Controlled Atrial Fibrillation[56] n=22 (mean)*	Rate-Controlled Atrial Fibrillation n=47 (mean ±1.0 SD)
Summary scales	Physical Component Summary (PCS)	30.6	42.9 ±11.3
	Mental Component Summary (MCS)	38.5	53.2 ±8.8
Primary scales	Physical Functioning (PF)	34.1	67.7 ±28.6
	Role-Physical (RP)	7.2	59.6 ±39.5
	Bodily Pain (BP)	45.0	75.1 ±27.0
	General Health (GH)	48.0	64.9 ±20.6
	Vitality (VT)	24.3	56.6 ±28.5
	Social Functioning (SF)	41.1	79.5 ±27.3
	Role-Emotional (RE)	28.3	83.7 ±31.8
	Mental Health (MH)	58.3	79.7 ±16.1

* SD for inadequately rate-controlled AF patients was not published

Yale Physical Activity Survey

The participants in the original YPAS study were recruited strictly from the

community, and only healthy volunteers were enrolled. It is not surprising that the YPAS

study participants reported greater physical activity levels than participants in this study

since the AF and NSR patients both have significant levels of comorbidity in contrast to

the healthy YPAS volunteers.

Nonetheless, the physical capacity of AF group was equal to that of the NSR

group. As for the Activities Dimensions, the AF and NSR Summary Indices were within

0.01 SD of each other. On the Activities Checklist, the AF group reported a mean Total

Time of 21.1 hours per week spent on physical activities versus the NSR group with 21.8

hours per week (refer to Table 12). AF patients report a physical capacity equal to that of

comparable age-matched patients in NSR.

TABLE 12 YALE PHYSICAL ACTIVITY SURVEY

			Healthy YPAS Study[*,57] Participants n=76	Atrial Fibrillation n=47	Normal Sinus Rhythm n=47	p-value[†]
Activities checklist	Total Time (hours per week)		32.5 ±17.6	21.1 ±17.2	21.8 ±17.6	0.85
	Total Energy (kcals per week)		7176 ±4385	4819 ±4321	5331 ±4808	0.60
Activities dimensions indices	Summary	(0-137)	46.9 ±24.3	27.7 ±14.7	27.5 ±13.2	0.98
	Vigorous	(0-60)	14.9 ±18.6	3.0 ±8.8	0.64 ±2.5	0.09
	Leisure Walking	(0-48)	16.4 ±12.5	10.8 ±12.7	11.5 ±11.8	0.79
	Moving	(0-15)	8.4 ±3.7	8.4 ±3.5	9.0 ±3.4	0.35
	Standing	(0-10)	4.7 ±2.4	3.8 ±2.3	4.3 ±2.7	0.31
	Sitting	(0-4)	2.0 ±0.7	2.2 ±1.0	2.2 ±0.9	0.75

* Healthy volunteers recruited from community with a mean age of 71.0 years
† AF versus NSR group, p-value by two-tailed paired t-test

Correlation of Comorbidity with Quality of Life and Physical Capacity

Since there was a marginally statistically significant difference in the degree of

comorbidity between the AF and NSR groups, the SF-36 scales and the YPAS indices

were tested for possible correlation with the Charlson Comorbidity Index. Pearson

correlation coefficients were calculated by the least-squares method for each of the SF-36

scales and each of the YPAS indices (refer to Table 13). Except for Role-Emotional, all

of the SF-36 scales had statistically significant negative correlation with the Charlson

Comorbidity Index. For example, the PCS Pearson correlation coefficient was -0.47

(p<0.0001, refer to Figure 1). On the other hand, none of the YPAS indices had

statistically significant correlation with the Charlson Comorbidity Index. The Pearson

correlation coefficients were -0.10 for the Total Time (p=0.34), and -0.17 for the

Summary Index (p=0.11). The Charlson Comorbidity Index correlates negatively with

the SF-36 scales whereas no such correlation exists with any of the YPAS indices.

Adjustment of SF-36 Scales

Because the SF-36 scales, except for Role-Emotional (RE), have a negative

correlation with comorbidity, scores for the SF-36 scales were adjusted for Charlson

Comorbidity Index (refer to Table 14). The SF-36 scores were adjusted by linear

regression using the least means squared method. With correction, the AF and NSR

groups' PCS and MCS scores were within 0.06 SD and 0.13 SD, respectively (p>0.05).
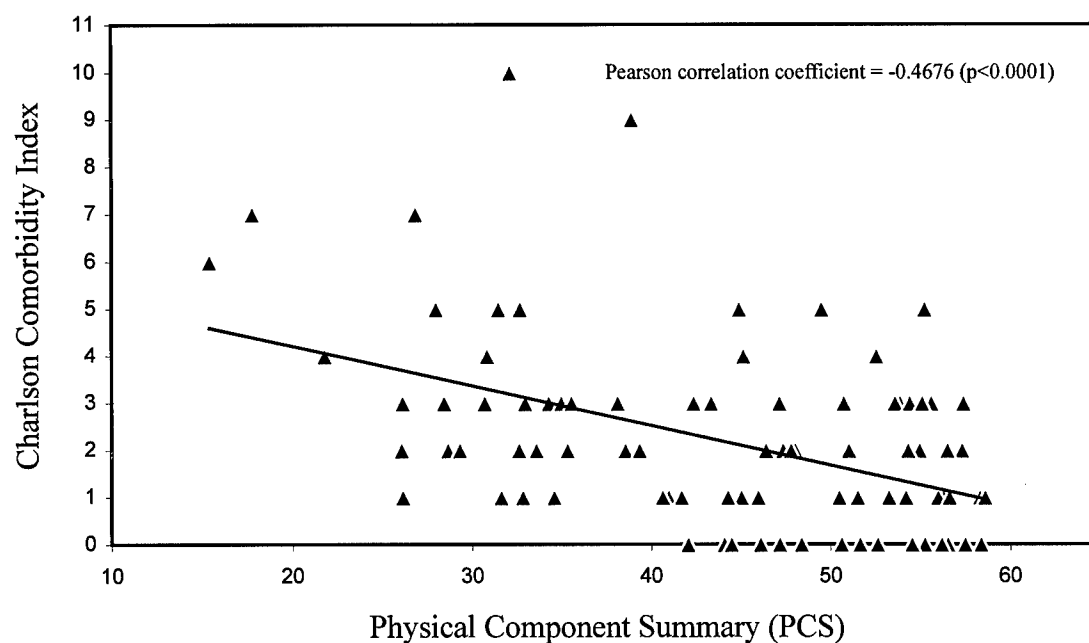
Figure 1   Correlation of SF-36 Physical Component Summary with Charlson Comorbidity Index (n=94)

TABLE 13 CORRELATION OF SHORT FORM HEALTH SURVEY (SF-36) AND YALE
PHYSICAL ACTIVITY SURVEY (YPAS) WITH THE CHARLSON
COMORBIDITY INDEX

			Pearson correlation coefficient	p-value
SF-36 Scales	Summary scales	Physical Component Summary (PCS)	-0.47	<0.0001
		Mental Component Summary (MCS)	-0.27	<0.05
	Primary scales	Physical Functioning (PF)	-0.40	<0.0001
		Role-Physical (RP)	-0.38	<0.001
		Bodily Pain (BP)	-0.43	<0.0001
		General Health (GH)	-0.34	<0.001
		Vitality (VT)	-0.31	<0.01
		Social Functioning (SF)	-0.38	<0.0001
		Role-Emotional (RE)	-0.12	0.2419
		Mental Health (MH)	-0.34	<0.001
Yale Physical Activity Survey	Activities checklist	Total Time (hours per week)	-0.10	0.3430
		Energy (kcals per week)	-0.14	0.1669
	Activities dimensions indices	Summary	-0.17	0.1117
		Vigorous Activities	-0.01	0.8914
		Leisure Walking	-0.11	0.2843
		Moving	-0.19	0.0647
		Standing	-0.10	0.3224
		Sitting	0.03	0.7562

TABLE 14 SHORT FORM HEALTH SURVEY (SF-36) CORRECTED FOR CHARLSON COMORBIDITY INDEX[*]

		Atrial Fibrillation n=47 (scale ±1.0 SD)	Normal Sinus Rhythm n=47 (scale ±1.0 SD)	Δ[**] (NSR – AF)
Summary scales	Physical Component Summary (PCS)	44.0 ±11.3	44.7 ±10.5	+0.7
	Mental Component Summary (MCS)	53.7 ±8.8	54.8 ±8.5	+1.1
Primary scales	Physical Functioning (PF)	70.1 ±28.6	73.4 ±26.8	+3.3
	Role-Physical (RP)	62.8 ±39.5	68.6 ±37.8	+5.8
	Bodily Pain (BP)	77.7 ±27.0	75.2 ±24.2	-2.5
	General Health (GH)	66.4 ±20.6	66.0 ±20.3	-0.4
	Vitality (VT)	58.4 ±28.5	62.2 ±21.9	+3.8
	Social Functioning (SF)	81.8 ±27.3	86.9 ±21.3	+5.1
	Mental Health (MH)	81.2 ±16.1	78.6 ±19.0	-2.6

  * SF-36 scores were corrected by linear regression using the least means squared method
 ** p>0.05 for all of the SF-36 scales

DISCUSSION

Almost all the AF patients in the study were medically managed with anticoagulation (95.7%) and rate-control (93.6%). The AF group demonstrated adequate rate-control with a mean heart rate of 73 ±11 and a maximal heart rate of 130 ±25 by 24-hour holter monitoring. Although the AF group had a higher Charlson Comorbidity Index of marginal statistical significance, both the AF and NSR groups demonstrated a significant level of comorbidity. The AF group had a mean of 4.4 ±2.1 and the NSR group had a mean of 3.0 ±1.8 medical conditions. The SF-36 scales and the YPAS indices failed to reveal any statistically significant difference between the rate-controlled AF group and the NSR group. Rate-controlled AF patients report QOL and physical capacity equal to comparable patients in NSR.

Quality of life

The AF group demonstrated QOL equal to the NSR group by SF-36 scores. The PCS was 44.0 for the AF group and 44.7 for the NSR group. As for the MCS, the AF and NSR groups scored 53.7 and 54.8, respectively. Differences of this magnitude, 0.7 on the PCS and 1.1 on the MCS, correspond with the impact of allergy or difficulty hearing on QOL (refer to Table 15).

The SF-36 scores for the NSR group were validated against age and sex-specific normative data. The PCS and MCS for the NSR group were statistically significantly greater than the normative data by 0.35 SD and 0.31 SD, respectively. The slightly increased QOL in the NSR group is most likely because the general population normative data included participants with all cardiac rhythms and participants with severely

debilitating disease. Nonetheless, the AF group demonstrated QOL equal to that of the NSR group.

TABLE 15   EFFECTS OF SELECTED CHRONIC CONDITIONS ON SF-36 SCORES IN THE GENERAL POPULATION[58]

	n	PCS Δ	MCS Δ
Allergy	842	-0.82*	0.04
Angina	112	-3.67**	0.18
Chronic lung disease	194	-3.12***	-3.03**
Congestive heart failure	93	-6.72***	-1.36
Diabetes	156	-3.44***	0.30
Hearing impairment	405	-0.94	-1.16*
Hypertension	701	-1.53***	-0.10

* p<0.05
** p<0.01
*** p<0.0001

On the other hand, the rate-controlled AF patients demonstrated significantly better QOL than the inadequately rate-controlled AF patients in previously published studies (refer to Table 11). The rate-controlled AF patients had PCS and MCS scores which were 1.1 SD and 1.7 SD, respectively, higher than the inadequately rate-controlled AF patients. Although the QOL is remarkably impaired in poorly rate-controlled AF patients, rate-controlled AF patients demonstrate QOL equal to NSR patients.

Physical Capacity

Physical capacity was assessed by the YPAS. The AF group demonstrated a physical capacity equal to that of the NSR group. The AF and NSR groups were within 0.04 SD on the Total Time Index, and within 0.01 SD on the Summary Index.

Coexistent Medical Conditions

The enrolled AF and NSR patients had a significant degree of comorbidity with a mean of 4.4 ±2.1 and 3.0 ±1.8 medical conditions, respectively. The AF and NSR groups were comparable in terms of comorbidity although the AF group had a higher Charlson Comorbidity Index, 2.6 versus 1.7, with marginal statistical significance (p=0.05).

Limitations

The conclusions of the study may be generalized to AF patients medically managed on anticoagulation and rate-control. A significant number of patients in AF may have contraindications to anticoagulation including chronic alcoholism, history of gastrointestinal hemorrhage, and uncontrolled hypertension. AF patients lacking either anticoagulation or rate-control will most likely demonstrate significantly impaired QOL and physical capacity.

Although a greater proportion of the AF patients were excluded for recent hospitalization, the non-elective hospitalizations in the AF patients most likely were secondary to inadequate rate-control leading to cardiac decompensation. The study was designed to specifically examine stable AF patients who are medically managed on anticoagulation and rate-control.

The 94 patient sample size limited the statistical power of the study to detecting differences on the order of 3-points for the SF-36 PCS and MCS scales. The AF group scored 0.7 points lower on the PCS and 1.1 points lower on the MCS than the NSR group. Even if the sample size were increased to 1572 patients, the detectable difference would bear at most the clinical significance of allergy or difficulty hearing on QOL.

Conclusion

Rate-controlled AF patients demonstrate QOL equal to NSR patients by SF-36 scores. The AF and NSR groups scored 44.0 and 44.7 on the PCS, a difference of 0.06 SD. On the MCS, the AF and NSR groups scored 53.7 and 54.8, respectively. The rate-controlled AF group demonstrated a physical capacity equal to the NSR group by the YPAS. The AF and NSR groups scored 27.7 and 27.5 on the Summary Index, a difference of 0.01 SD. The Total Time for physical activities was 21.1 and 21.8 hours per week, respectively, for the AF and NSR groups.

Rate-controlled AF patients demonstrate QOL and physical capacity equal to that of comparable age-matched NSR patients. Rhythm control does not appear to offer any QOL or physical capacity benefit for patients who can be managed on anticoagulation and rate-control. The ongoing Atrial Fibrillation Follow-up Investigation of Rhythm Management (AFFIRM) and the VA clinical trials will further address the issue of appropriate management of atrial fibrillation.

APPENDIX A – PAST MEDICAL HISTORY

In reviewing the chart, does the patient have a documented past medical or surgical history[*] of any of the following:

	Yes	No
Percutaneous transluminal coronary angioplasty?		
Coronary artery bypass grafting?		
Hypercholesterolemia?		
Thyroid disorder?		
Syncope?		
Myocardial infarction?		
Congestive heart failure?		
Peripheral vascular disease?		
Cerebrovascular disease?		
Dementia?		
Chronic pulmonary disease?		
Connective tissue disease?		
Peptic ulcer disease?		
Mild liver disease?		
Moderate to severe liver disease?		
Diabetes?		
Diabetes with end organ damage?		
Hemiplegia?		
Moderate to severe renal disease?		
Severe renal disease?		
Tumor?		
Leukemia?		
Lymphoma?		
Metastatic solid tumor?		
Acquired immune deficiency syndrome?		
Angina?		
Arrhythmia?		
Valvular heart disease?		
Hypertension?		
Paralysis?		
Neurologic conditions?		
Moderate renal insufficiency?		
Endocrine disorders?		
Inflammatory bowel disease?		
Gastrointestinal bleeding?		
Rheumatologic disease?		
Coagulopathy?		

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[*] Refer to Appendix C for specific definitions of each medical condition

APPENDIX B – MEDICATIONS REVIEW

Does the patient have active prescriptions for:

	Yes	No
Warfarin?		
Aspirin?		
Angiotensin converting enzyme inhibitor?		
Beta-adrenergic blockers?		
Calcium channel blockers?		
Diuretics?		
Digoxin?		
Antiarrhythmics?		
Pulmonary medications?		
Diabetic medications?		
Psychiatric medications?		

How many active prescriptions does the patient have? _____

APPENDIX C – DEFINITIONS

Condition	Definition[59]
Angina	Chronic exertional angina, or history of CABG
Myocardial infarction	Definite or probable MI; hospitalization and either ECG changes or elevated myocardial enzymes; ECG changes alone do not suffice
Congestive heart failure	Exertional or paroxysmal nocturnal dyspnea with response to digitalis, diuretics, or afterload reducing agents
Arrhythmia	Chronic atrial fibrillation, atrial flutter, sick sinus syndrome, or ventricular arrhythmias requiring chronic treatment
Valvular disease	Hemodynamically significant aortic stenosis or insufficiency; prosthetic aortic or mitral valves; symptomatic mitral valve prolapse, asymmetric septal hypertrophy requiring treatment, or tricuspid insuffiency
Peripheral vascular disease	Intermittent claudication, or previous bypass for arterial insufficiency; history of gangrene or acute arterial insufficiency; untreated thoracic or abdominal aneurysm (6 cm or greater)
Hypertension	Persistently elevated systolic or diastolic BP; controlled hypertension
Cerebrovascular disease	History of stroke with minor or no residua; transient ischemic attacks
Paralysis	Dense hemiplegia or paraplegia whether by CVA or otherwise
Dementia	Chronic cognitive deficit
Neurologic conditions	Parkinson's disease, uncontrolled seizures, or syncope without identifiable cause or treatment
Mild pulmonary disease	Dyspnea with moderate activity without treatment, or dyspnea only with attacks (e.g. asthma)
Moderate pulmonary disease	Dyspnea with slight activity; or with moderate activity despite treatment
Severe pulmonary disease	Dyspnea at rest despite treatment; oxygen-dependent; CO_2 retained, or baseline PO_2 below 50 torr
Severe diabetes	Retinopathy, neuropathy, or nephropathy
Moderate diabetes	Previous hospitalization for ketoacidosis, hyperosmolar coma or control; juvenile onset or brittle diabetes
Mild diabetes	Treated with insulin or oral hypoglycemic, but not by diet alone
Endocrine disorder	Hypopituitarism, adrenal insufficiency and recurrent acidosis
Severe renal disease	Dialysis dependent; previous transplant; history of uremia
Moderate renal insufficiency	Serum creatinine greater than 3mg%
Mild renal insufficiency	Serum creatinine of 2-3 mg%
Severe liver disease	Cirrhosis and portal hypertension with a history of variceal bleeding
Moderate liver disease	Cirrhosis and portal hypertension without a history of variceal bleeding
Mild liver disease	Cirrhosis without portal hypertension or chronic hepatitis
Inflammatory bowel disease	Ulcerative colitis or regional enteritis
Peptic ulcer disease	Required treatment for ulcer disease including previous bleed from ulcer
Gastrointestinal bleeding	Requiring transfusion from causes other than ulcer disease
Acquired immune deficiency syndrome	AIDS, or AIDS related complex
Lymphoma	Hodgkins lymphosarcoma, Waldenstrom's macroglobulinemia, myeloma, and other lymphomas

APPENDIX C – DEFINITIONS (continued)

Leukemia	Acute and chronic myelogenous leukemia; acute and chronic lymphocytic leukemia; polycythemia vera
Metastatic cancer	Metastatic solid tumors including breast, lung, colon etc.
Tumor	Solid tumor without documented metastases but initially treated in the last five years
Rheumatologic	Systemic lupus erythematosis, polymyositis, mixed connective tissue disease, polymyalgia rheumatica, and moderate to severe rheumatoid arthritis
Coagulopathy	Circulating anticoagulant or other coagulopathy

APPENDIX D – DEMOGRAPHIC DATA AND SOCIAL HISTORY

1. Where do you live?

    House 1

    Apartment 2

    Mobile home 3

    Senior housing 4

    With relatives (other than spouse) 5

    Homeless..6

    Other 7

2. Do you live alone?

    Yes 1

    No...2

3. Do you live with your spouse or significant other?

    Yes 1

    No...2

4. Do have any children that live with you?

    Yes 1

    No...2

5. Do you live with any other relative?

    Yes 1

    No...2

6. Do you have a paid employee in living in your household?

        Yes 1

        No..2

7. Do you have anyone else not mentioned above living in your household?

        Yes 1

        No..2

8. What is the total number of household members including yourself? _____

9. What is the highest level of education you completed?

        No formal education. 1

        Elementary school (grades 1 to 8) 2

        High school (grades 9 to 12)...3

        Some college or vocational school 4

        College or vocational school graduate.................................5

        Postgraduate education 6

10. Are you currently working or retired?

        Working 1

        Retired...2

11. How many hours per week do you work? _____

12. How many hours per week do you volunteer somewhere? _____

13. What type of work did you do most of your life?

   Management...1

   Office work 2

   Factory work 3

   Construction work.......................................4

   Homemaker...5

   Other 6

   Not applicable 7

14. Is there anyone with whom you are close?

   Yes 1

   No...2

15. Is there anyone who you can count on for help?

   Yes 1

   No...2

16. Is there anyone who you can rely on for emotional support?

   Yes 1

   No...2

17. What is your current marital status?

        Married...1

        Single 2

        Widowed..3

        Separated..4

        Divorced...5

18. What is your smoking history?

        Current smoker..1

        Former smoker 2

        Never smoked 3

19. If you are a former smoker, how many years ago did you quit? _____

20. How many packs per day on the average did you, or do you smoke? _____

21. How many years have you smoked? _____

22. What is your history of alcohol use?

        Current alcohol use 1

        Former alcohol use..2

        Never used alcohol..3

23. How many days out of a month do you drink alcohol?

    Less than 1 day..1

    1 to 3 days...2

    4 to 7 days...3

    8 to 15 days...4

    16 to 24 days...5

    More than 24 days..6

    Not applicable...7

24. How many bottles of beer do you drink in one day? _____

25. How many glasses of wine do you drink in one day? _____

26. How many shots of hard liquor do you drink in one day? _____

27. What is your height? _____

28. What is your weight? _____

29. Have you ever been cardioverted—i.e. have you ever had electrical shocks to your chest, or been given any medications to change the rhythm of your heart?

    Yes 1

    No...2

    Not applicable 3

30. How many times has cardioversion been attempted? _____

APPENDIX E – SHORT FORM HEALTH SURVEY (SF-36)

Standardized Booklet Version[60]

1. In general, would you say your health is:

        Excellent 1

        Very good...2

        Good...3

        Fair 4

        Poor..5

2. Compared to one year ago, how would you rate your health in general now?

        Much better now than one year ago 1

        Somewhat better now than one year ago 2

        About the same as one year ago..3

        Somewhat worse now than one year ago...............................4

        Much worse now than one year ago 5

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	YES, LIMITED A LOT	YES, LIMITED A LITTLE	NO, NOT LIMITED AT ALL
a. **Vigorous activities,** such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. **Moderate activities,** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing **several** flights of stairs	1	2	3
e. Climbing **one** flight of stairs	1	2	3
f. Bending, kneeling, or stooping	1	2	3
g. Walking **more than a mile**	1	2	3
h. Walking **several blocks**	1	2	3
i. Walking **one block**	1	2	3
j. Bathing or dressing yourself	1	2	3

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	YES	NO
a. Cut down on the **amount of time** you spent on work or other activities	1	2
b. **Accomplished less** than you would like to	1	2
c. Were limited in the **kind** of work or other activities	1	2
d. Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	YES	NO
a. Cut down on the **amount of time** you spent on work or other activities	1	2
b. **Accomplished less** than you would like	1	2
c. Didn't do work or other activities as **carefully** as usual	1	2

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all..1

Slightly..2

Moderately 3

Quite a bit..4

Extremely..5

7. How much bodily pain have you had during the past 4 weeks?

None...1

Very mild 2

Mild...3

Moderate 4

Severe..5

Very severe 6

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all..1

A little bit...2

Moderately 3

Quite a bit..4

Extremely..5

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

	ALL OF THE TIME	MOST OF THE TIME	A GOOD BIT OF THE TIME	SOME OF THE TIME	A LITTLE OF THE TIME	NONE OF THE TIME
a. did you feel full of pep?	1	2	3	4	5	6
b. have you been a very nervous person?	1	2	3	4	5	6
c. have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d. have you felt calm and peaceful?	1	2	3	4	5	6
e. did you have a lot of energy?	1	2	3	4	5	6
f. have you felt downhearted and blue?	1	2	3	4	5	6
g. did you feel worn out?	1	2	3	4	5	6
h. have you been a happy person?	1	2	3	4	5	6
i. did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?

All of the time 1

Most of the time 2

Some of the time 3

A little of the time 4

None of the time...5

11. How TRUE or FALSE is each of the following statements for you?

	DEFINITELY TRUE	MOSTLY TRUE	DON'T KNOW	MOSTLY FALSE	DEFINITELY FALSE
a. I seem to get sick a little easier than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

APPENDIX F – YALE PHYSICAL ACTIVITY SURVEY

Physical Activities Checklist[61]

For each activity you do below, please tell me how much time, in hours, you spent doing this activity during a <u>typical week</u> over the past month:

		Time (hours per week)	Intensity[62,63] (kcals per minute)
Work Activities	Shopping (eg. grocery or clothes)		3.5
	Climbing stairs while carrying a load		8.5
	Laundry (time loading, unloading, hanging, folding)		3.0
	Light housework (tidying, dusting, sweeping, collecting trash in home, polishing, indoor gardening, ironing)		3.0
	Heavy housework (vacuuming, mopping, scrubbing floors and walls, moving furniture or boxes, taking out the garbage cans)		4.5
	Food preparation (more than 10 minutes in duration; chopping, stirring, moving about to get food items or pans)		2.5
	Food service (more than 10 minutes in duration; setting the table, carrying food, serving food)		2.5
	Dishwashing (more than 10 minutes in duration; clearing the table; washing, drying, or putting the dishes away)		2.5
	Light home repair (small appliance repair; light home maintenance or repair)		3.0
	Heavy home repair (painting; carpentry; washing or polishing the car)		5.5
	Other work activity:		
Yardwork	Gardening (planting, weeding, digging or hoeing)		4.5
	Lawn mowing (only if pushing lawn mower)		4.5
	Clearing walks or driveway (sweeping, shoveling or raking)		5.0
	Other yardwork:		
Caretaking	Caring for an older or disabled person (including lifting person or pushing wheelchair)		5.5
	Childcare (lifting child, carrying child, pushing stroller)		4.0
Exercise	Brisk walking (more than 10 minutes in duration)		6.0
	Pool exercises, stretching, yoga		3.0
	Vigorous calisthenics or aerobics		6.0
	Cycling or exercise cycle		6.0
	Swimming laps		6.0
	Other exercise:		
Recreational Activities	Leisure walking (more than 10 minutes in duration)		3.5
	Needlework (knitting, sewing, needlepoint etc.)		1.5
	Dancing (moderate to fast)		5.5
	Bowling or bocci		3.0
	Golf (only without golfcart)		5.0
	Racquet sports (tennis, racquet ball)		7.0
	Billiards		2.5
	Other recreational activity:		

Physical Activities Dimensions

1. About how many times during the month did you participate in vigorous activities that lasted at least 10 minutes and caused you to perspire, or caused large increases in breathing, heart rate, or leg fatigue?

       Not at all...0

       One to three times per month................................1

       One to two times per week....................................2

       Three to four times per week 3

       Five or more times per week..................................4

       Refused 7

       Don't know...8

2. About how long do you do this vigorous activity each time?

       Not applicable 0

       Ten to thirty minutes..1

       Thirty-one to sixty minutes...................................2

       More than sixty minutes.......................................3

       Refused 7

       Don't know...8

3. Think about the walks you have taken during the past month. About how many times per month did you walk for 10 minutes or more without stopping which was not strenuous enough to cause you to perspire, or cause large increases in breathing, heart rate, or leg fatigue?

Not at all...0

One to three times per month....................................1

One to two times per week...2

Three to four times per week 3

Five or more times per week.......................................4

Refused 7

Don't know..8

4. When you did this walking, for how many minutes did you do it?

Not applicable 0

Ten to thirty minutes...1

Thirty-one to sixty minutes......................................2

More than sixty minutes...3

Refused 7

Don't know..8

5. About how many hours a day do you spend moving around on your feet while doing things? Please report only the time that you are actually moving.

Not at all..0

Less than one hour per day 1

One to less than three hours per day 2

Three to less than five hours per day 3

Five to less than seven hours per day.......................................4

Seven hours or more per day 5

Refused 7

Don't know...8

6. Think about the time you spend standing or moving around on your feet on an average day during the past month. About how many hours per day do you stand?

Not at all..0

Less than one hour per day 1

One to less than three hours per day 2

Three to less than five hours per day 3

Five to less than seven hours per day.......................................4

Seven hours or more per day 5

Refused 7

Don't know...8

7. About how many hours did you spend sitting on an average day during the past month?

> Not at all 0
>
> Less than three hours 1
>
> Three to less than six hours 2
>
> Six to less than eight hours 3
>
> More than eight hours 4
>
> Refused 7
>
> Don't know 8

8. How many flights of stairs do you climb up each day (ten steps is equal to one flight)? _____

9. Please compare the amount of physical activity that you do during other seasons of the year with the amount of activity you just reported for a typical week in the past month. For example, in the Spring, do you do more or less activity than what you reported for the past month?

	A lot more	A little more	The same	A little less	A lot less	Don't know
Spring	1.30	1.15	1.00	0.85	0.70	N/A
Summer	1.30	1.15	1.00	0.85	0.70	N/A
Fall	1.30	1.15	1.00	0.85	0.70	N/A
Winter	1.30	1.15	1.00	0.85	0.70	N/A

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